

# BEST AVAILABLE COPY

PCT/US00/22583

## PATENT COOPERATION TREATY

PCT

### NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Commissioner  
US Department of Commerce  
United States Patent and Trademark  
Office, PCT  
2011 South Clark Place Room  
CP2/5C24  
Arlington, VA 22202  
ETATS-UNIS D'AMERIQUE  
in its capacity as elected Office

Date of mailing (day/month/year)  
11 July 2001 (11.07.01)

International application No.  
PCT/US00/22583

Applicant's or agent's file reference  
GMV-003.25

International filing date (day/month/year)  
17 August 2000 (17.08.00)

Priority date (day/month/year)  
25 August 1999 (25.08.99)

Applicant

NICOLAU, Yves, Claude et al

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:  
23 March 2001 (23.03.01)

☐ in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was  
☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO  
34, chemin des Colombettes  
1211 Geneva 20, Switzerland

Facsimile No.: (41-22) 740.14.35

Authorized officer

H. Zhou

Telephone No.: (41-22) 338.83.38

Form PCT/IB/331 (July 1992)

US0022583

# PATENT COOPERATION TREATY

# PCT

REC'D 19 OCT 2001

## INTERNATIONAL PRELIMINARY EXAMINATION ~~WORK~~REPORT

(PCT Article 36 and Rule 70)



14

Applicant's or agent's file reference GMV-003.25	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416)	
International application No. PCT/US00/22583	International filing date (day/month/year) 17/08/2000	Priority date (day/month/year) 25/08/1999
International Patent Classification (IPC) or national classification and IPC A61K31/575		
Applicant GMP COMPANIES, INC. et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.
  - ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:
  - I ☒ Basis of the report
  - II ☐ Priority
  - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
  - IV ☐ Lack of unity of invention
  - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
  - VI ☐ Certain documents cited
  - VII ☐ Certain defects in the international application
  - VIII ☒ Certain observations on the international application

Date of submission of the demand 23/03/2001	Date of completion of this report 17.10.2001
Name and mailing address of the International preliminary examining authority:  European Patent Office D-80299 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Herz, C Telephone No. +49 89 2399 8275 

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/US00/22583

**I. Basis of the report**

1. With regard to the elements of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, pages:

1-48 as originally filed

Claims, No.:

1-49 as originally filed

Drawings, sheets:

1-2 as originally filed

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/US00/22583

☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

*(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

6. Additional observations, if necessary:

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Yes:	Claims	1-49
	No:	Claims	
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-49
Industrial applicability (IA)	Yes:	Claims	1-49
	No:	Claims	

2. Citations and explanations  
see separate sheet

**VIII. Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:  
see separate sheet

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT - SEPARATE SHEET**

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International application No. PCT/US00/22583

possess this property (Article 33 (3) PCT).

## PATENT COOPERATION TREATY

## PCT

## INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference <b>GMV-003.25</b>	<b>FOR FURTHER ACTION</b> see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. <b>PCT/US 00/ 22583</b>	International filing date (day/month/year) <b>17/08/2000</b>	(Earliest) Priority Date (day/month/year) <b>25/08/1999</b>
Applicant <b>GMP COMPANIES, INC. et al.</b>		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 8 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

**1. Basis of the report**

- a. With regard to the language, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

- b. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international search was carried out on the basis of the sequence listing :

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. ☒ Certain claims were found unsearchable (See Box I).

3. ☐ Unity of invention is lacking (see Box II).

4. With regard to the title,

☐ the text is approved as submitted by the applicant.

☒ the text has been established by this Authority to read as follows:

**AGENTS FOR THE ENHANCED OXYGEN DELIVERY IN MAMMALS**

5. With regard to the abstract,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the drawings to be published with the abstract is Figure No.

☐ as suggested by the applicant.

☐ because the applicant failed to suggest a figure.

☐ because this figure better characterizes the invention.

☒ None of the figures.

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US 00/22583

## Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☒ Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:  
see FURTHER INFORMATION sheet PCT/ISA/210
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

## INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 00/22583

A. CLASSIFICATION OF SUBJECT MATTER  
IPC 7 A61K31/575 A61K31/70

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)

CHEM ABS Data

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y ✓	EP 0 338 916 A (INSTITUT MERIEUX) 25 October 1989 (1989-10-25) claims 1-34	1-49
Y ✓	WO 97 42819 A (A. HACES) 20 November 1997 (1997-11-20) claims 1-19	1-49
Y ✓	WO 98 39358 A (GENTA INC.) 11 September 1998 (1998-09-11) claims 1-38	1-49
Y ✓	WO 98 39359 A (GENTA INC.) 11 September 1998 (1998-09-11) claims 1-41	1-49
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☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

## \* Special categories of cited documents:

\*A\* document defining the general state of the art which is not considered to be of particular relevance

\*E\* earlier document but published on or after the international filing date

\*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

\*O\* document referring to an oral disclosure, use, exhibition or other means

\*P\* document published prior to the international filing date but later than the priority date claimed

\*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

\*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

\*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

\*&\* document member of the same patent family

Date of the actual completion of the international search

2 January 2001

Date of mailing of the international search report

2. 02. 01

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
Fax (+31-70) 340-3016

Authorized officer

Herz, C



International Application No  
PCT/US 00/22583

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Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	✓ EP 0 452 055 A (HEWLETT-PACKARD CO.) 16 October 1991 (1991-10-16) claims 1-16	1-49
Y	✓ US 5 612 207 A (Y. C. NICOLAU ET AL.) 18 March 1997 (1997-03-18) column 23, line 15 -column 24, line 25	1-49
Y	✓ US 5 927 283 A (D. J. ABRAHAM, M. GERBER) 27 July 1999 (1999-07-27) claims 1,2; tables 1-7	1-49
Y	✓ US 5 872 282 A (D. J. ABRAHAM ET AL.) 16 February 1999 (1999-02-16) tables 1-7	1-49
Y	✓ US 5 110 909 A (E. DELLACHERIE ET AL.) 5 May 1992 (1992-05-05) claims 1-23	1-49
Y	✓ US 4 921 997 A (I. LALEZARI, P. LALEZARI) 1 May 1990 (1990-05-01) table 1	1-49
Y	✓ US 5 079 337 A (M. LEONARD ET AL.) 7 January 1992 (1992-01-07) claims 1-29	1-49
Y	✓ PATENT ABSTRACTS OF JAPAN vol. 017, no. 119, 12 March 1993 (1993-03-12) & JP 04 300838 A (TERUMO CORP.), 23 October 1992 (1992-10-23) abstract	1-49
Y	✓ E. ANTONINI ET AL.: "The Effect of Anions and Cations on the Oxygen Equilibrium of Human Hemoglobin" OXYGEN AFFINITY HEMOGLOBIN RED CELL ACID BASE STATUS, PROC. ALFRED BENZON SYMP., 4TH (25YHA4), 1972, pages 121-130, XP000944291 figures 1-4	1-49
Y	✓ N. OUDHIRI ET AL.: "Guanidinium-cholesterol cationic lipids: novl reagents for gene transfection and perspectives for gene therapy" BIOGENIC AMINES, vol. 14, no. 5, 1998, pages 537-552, XP000944064 figure 1	1-49

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## INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 00/22583

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y ✓	W. J. FANTL ET AL.: "Specifically Carboxymethylated Hemoglobin as an Analogue of Carbamino Hemoglobin" J. BIOL. CHEM., vol. 262, no. 26, 1987, pages 12700-12713, XP000943847 page 12700	1-49
Y ✓	K. UCHIDA ET AL.: "Effect of an Allosteric Modifier of Hemoglobin, RSR-4, on Oxygen Affinity and Oxygen Saturation of Hemoglobin in Rabbits" JPN. J. PHYSIOL., vol. 48, no. 6, 1998, pages 439-444, XP000943772 table 2	1-49
Y ✓	I. PAPASSOTIRIOU ET AL.: "Synthesized allosteric effectors of the hemoglobin molecule: A possible mechanism for improved erythrocyte oxygen release capability in hemoglobinopathy H disease" EXPERIMENTAL HEMATOLOGY, vol. 26, no. 10, 1998, pages 922-926, XP000943784 figures 1-4; tables 1,2	1-49
Y ✓	I. TABUSHI ET AL.: "Artificial Allosteric Molecules - Especially Focusing upon Allosteric O <sub>2</sub> Binding Molecules of the Hemoglobin Type" MOL. STRUCT. ENERG., vol. 10, 1988, pages 195-218, XP000943789 tables 7-6	1-24
Y ✓	C. NADOLNY ET AL.: "Specific Interactions of the Allosteric Effector 2,3-Bisphosphoglycerate with Human Hemoglobin - A Difference FTIR Study" BIOL. CHEM. HOPPE-SEYLER, vol. 374, no. 6, 1993, pages 403-407, XP000943782 * entire document *	1-49
Y ✓	K. S. KILGORE ET AL.: "RSR13, a Synthetic Allosteric Modifier of Hemoglobin, Improves Myocardial Recovery Following Hypothermic Cardiopulmonary Bypass" CIRCULATION, SUPPL., vol. 100, no. 19, 1999, pages 351-356, XP000943791 figures 1-4; tables 1,2	1-49

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## INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 00/22583

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	✓ D. L. CURRELL ET AL.: "Synthetic polyphosphonates, polyphosphates, and phosphonocarboxylates as allosteric effectors of hemoglobin" PHOSPHORUS, SULFUR SILICON RELAT. ELEM., vol. 51-52, no. 1-4, 1990, pages 35-38, XP000943807 tables I-IV	1-49
Y	✓ A. N. CHUVILIN ET AL.: "Allosteric regulators of reversible hemoglobin oxygenation" BIOORG. KHIM., vol. 16, no. 9, 1990, pages 1157-1176, XP002156415 page 1176	1-49
Y	✓ J.-P. VIGNERON ET AL.: "Guanidinium-cholesterol cationic lipids: Efficient vectors for the transfection of eukaryotic cells" PROC. NATL. ACAD. SCI. USA, vol. 93, no. 18, 1996, pages 9682-9686, XP002030510 * entire document *	1-49
Y	✓ N. OUDRHIRI ET AL.: "Gene transfer by guanidinium-cholesterol cationic lipids into airway epithelial cells in vitro and in vivo" PROC. NATL. ACAD. SCI. USA, vol. 94, no. 5, 1997, pages 1651-1656, XP002035783 * entire document *	1-49
Y	✓ B. PITARD ET AL.: "Structural characteristics of supramolecular assemblies formed by guanidinium-cholesterol reagents for gene transfection" PROC. NATL. ACAD. SCI. USA, vol. 96, no. 6, 1999, pages 2621-2626, XP000941540 * entire documents *	1-49
Y	✓ US 5 599 974 A (D. J. ABRAHAM ET AL.) 4 February 1997 (1997-02-04) tables 1,2	1-49
Y	✓ WO 92 20335 A (CENTER FOR INNOVATIVE TECHNOLOGY) 26 November 1992 (1992-11-26) claims 1-12	1-49
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## INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 00/22583

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	✓ US 5 731 454 A (D. J. ABRAHAM ET AL.) 24 March 1998 (1998-03-24) column 29, line 1 -column 29, line 29 ---	1-49
Y	✓ US 5 432 191 A (D. J. ABRAHAM ET AL.) 11 July 1995 (1995-07-11) column 21, line 23 -column 22, line 5; table 4 ---	1-49
Y	✓ J.-P. VIGNERON: "Supramolecular Bioorganic Chemistry: Nucleic Acids Recognition and Synthetic Vectors for Gene Transfer" MOLECULES, vol. 4, 1999, pages 180-203, XP002156416 * entire document * -----	1-49

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 00/22583

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
EP 338916	A	25-10-1989	FR 2630329 A AT 77753 T DE 68901944 D DE 68901944 T ES 2043054 T GR 3005220 T JP 2042023 A US 5110909 A	27-10-1989 15-07-1992 06-08-1992 10-12-1992 16-12-1993 24-05-1993 13-02-1990 05-05-1992
WO 9742819	A	20-11-1997	NONE	
WO 9839358	A	11-09-1998	US 5877220 A AU 6687998 A	02-03-1999 22-09-1998
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US 5927283	A	27-07-1999	US 5677330 A US 5731454 A US 5432191 A US 5290803 A US 5122539 A US 5049695 A US 5382680 A US 5872282 A US 5591892 A US 5648375 A US 5705521 A US 5661182 A CA 2109575 A EP 0585366 A JP 3023423 B JP 7508973 T US 5250701 A WO 9220335 A US 5248785 A CA 2051693 A DE 69115790 D DE 69115790 T EP 0471811 A JP 3023422 B JP 4506812 T WO 9112235 A	14-10-1997 24-03-1998 11-07-1995 01-03-1994 16-06-1992 17-09-1991 17-01-1995 16-02-1999 07-01-1997 15-07-1997 06-01-1998 26-08-1997 26-11-1992 09-03-1994 21-03-2000 05-10-1995 05-10-1993 26-11-1992 28-09-1993 13-08-1991 08-02-1996 23-05-1996 26-02-1992 21-03-2000 26-11-1992 22-08-1991
US 5872282	A	16-02-1999	US 5731454 A US 5432191 A	24-03-1998 11-07-1995

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International Application No

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		US 5591892 A	07-01-1997
		US 5677330 A	14-10-1997
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# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 00/22583

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		JP 3023422 B	21-03-2000
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		US 5872282 A	16-02-1999
		US 5731454 A	24-03-1998
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		DE 69115790 D	08-02-1996
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**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT - SEPARATE SHEET**

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International application No. PCT/US00/22583

1. The Applicant is informed that this Opinion is based on the documents retrieved by the search. Due to the fact that this search was not carried out completely for all claims, since the scope of the claims are not clearly formulated this Examination Report cannot be complete.

2. From the state of the art as represented by the documents cited in the International Search Report numerous compounds which are similar in structure to compounds falling under the definition of Claim 11 are known to enhance the oxygen delivery in mammals.

Taking into account these facts the man skilled in the art would have to expect oxygen delivery enhancing capability without affecting their basic capabilities when modifying the basic moiety and/or the substituents of the groups of compounds disclosed in the state of the art. Thus representing only predictable effects the compounds claimed are considered to be obvious.

Consequently, Claims 1 to 49 are lacking inventive step under Article 33 (3) PCT.

3. The terms "lipophilic water-soluble molecule" and "ligand for a mammalian cellular receptor" are totally inappropriate in defining chemical compounds. The claims lack clarity (Article 6 PCT) since an attempt is made to define the compounds by reference to a result to be achieved rather than specifying their chemical structure by indicating the identity and number of the atoms involved.

Furthermore, the claims cover all products having this characteristic or property, whereas the application provides support within the meaning of Article 6 PCT and/or disclosure within the meaning of Article 5 PCT for only a very limited number of such products. In the present case, the claims so lack support, and the application so lacks disclosure.

With regard to the universe of different compounds falling under the scope of Claim 11 it is noted that a technical effect which justifies the selection of the claimed compounds must be one which can be assumed to be produced by substantially all the selected compounds. The numerous non-, mono- and polycyclic isocyclic and heterocyclic moieties being further substituted by numerous different groups as given in Claim 11 virtually encompass such an enormous number of compounds and that is by now way credible that all these variants represent solutions to the problem of providing improved  $\alpha$ -ammonium ketones as photoinitiators. There is no proven common general knowledge to show that the type of substituents that may be present in the claimed compounds would be irrelevant to the presence of the alleged properties.

For these reasons, and on the basis of what evidence there is in the case (only two actual working examples), the International Preliminary Examining Authority is not satisfied that substantially all compounds being claimed are likely to exhibit the alleged superior photoinitiating activity. Only those of the claimed compounds could possibly involve an inventive step which could be accepted as solutions of the technical problem of providing further compounds which